UNITED STATES DISTRICT COURT
DISTRICT OF NEW JERSEY

PFIZER INC., PHARMACIA CORP., PHARMACIA & UPJOHN INC., PHARMACIA& UPJOHN COMPANY, G.D. SEARLE & CO, G.D. SEARLE LLC, SEARLE LLC (DELAWARE) and SEARLE LLC (NEVADA) Plaintiffs, v. TEVA PHARMACEUTICALS USA, INC. Defendant.	CIV. ACTION NO. 04-754 (JCL) **OPINION** Teva's In Limine Motion No. 3

LIFLAND, District Judge

This case arises out of Teva Pharmaceuticals U.S.A., Inc.'s ("Teva" or "Defendant") alleged infringement of U.S. Patent Nos. 5,466,823; 5,563,165; and 5,760,068 (the "patents-in-suit"), which are held by Pfizer, Inc., Pharmacia Corp., Pharmacia & Upjohn Inc., Pharmacia & Upjohn Company, G.D. Searle & Co., G.D. Searle LLC, Searle LLC (Delaware), and Searle LLC (Nevada) (collectively "Pfizer" or "Plaintiffs"). The patents-in-suit are directed toward celecoxib, the active ingredient in Celebrex, and a broad genus of compounds that includes celecoxib, pharmaceutical compositions including such compounds, and methods

of using such compounds.

Before the Court is Teva's in limine motion No. 3 to preclude evidence of copying. It is well established that secondary considerations, such as commercial success, long-felt but unresolved need, unexpected results, copying, and the failure of others to develop the invention, must be considered as part of a court's obviousness analysis. See, e.g., Glaverbel Societe Anonyme v. Northlake Markeint & Supply, Inc., 45 F.3d 1550, 1555 (Fed. Cir. 1995). With respect to the secondary consideration of copying, "courts have considered deliberate copying of the patent holder's device by the defendant in an infringement suit as evidence tending to support [nonobviousness]." 2 Chisum on Patents § 5.05[5][a]; see also Diamond Rubber Co. V. Consolidated Rubber Tire Co., 220 U.S. 428, 441 (1911); Specialty Composites v. Cabot Corp., 845 F.2d 981, 991 (Fed. Cir. 1988) (noting that the infringer "closely copied the invention in the . . . patent," and explaining that "copying the claimed invention, rather than one in the public domain, is indicative of unobviousness") (internal quotation marks and citations omitted).

Teva argues, however, that evidence of copying is irrelevant in this case, and that Pfizer should therefore be precluded from offering such evidence under Federal Rules of Evidence 402 and 403. Specifically, Teva argues that evidence of copying is irrelevant in Hatch-Waxman Act cases, like this one, because the Act

"encourages the development of generic pharmaceuticals that 'copy' existing brand name drugs."[1] (Memorandum of Law in Support of Teva's in Limine Motion No. 3, at 1.) Teva cites Aventis Pharma Deutschland GmbH v. Lupin Ltd., No. 2:05CV421, 2006 U.S. Dist. LEXIS 48246 (E.D. Va. July 17, 2006), in support of its position. In Aventis, the United States District Court for the Eastern District of Virginia explained:

> As for copying, there is no question that Lupin [the defendant] attempted to copy Altace. That is what generic drug companies do. That is why their products are cheaper. As MOY'S WALKER ON PATENTS observes, however, "[the copying] rationale is considerably weakened . . . by the fact that there are various other reasons why an invention may have been copied." § 9:60 (4th ed. 2005). In this case, the reason why Lupin attempted to copy Altace is because the ANDA

[1] The Hatch-Waxman Amendments to the Federal Food, Drug, and Cosmetic Act permit an applicant to file an Abbreviated New Drug Application ("ANDA") with the Food and Drug Administration ("FDA") requesting approval of a bioequivalent ("generic") version of a drug that is already listed by the FDA as approved for safety and effectiveness without having to submit additional safety and efficacy data. See 21 U.S.C. § 355(j)(2)(A). An ANDA may be filed for drugs currently protected by patents. In its filing, the applicant must certify either (1) that it will not market its drug prior to the expiration of the relevant patents, or (2) that the relevant patents "are invalid or will not be infringed by the manufacture, use or sale of the new drug for which the ANDA is submitted." 21 U.S.C. § 355(j)(2)(A)(vii)(IV). An ANDA applicant filing its application with the FDA and making a Section IV certification must notify the holder of the patent, who may then bring an action against the applicant for infringement under 35 U.S.C. § 271(e)(2). See 21 U.S.C. §§ 355(j)(2)(B)(i) and (j)(5)(B)(iii). Submission of an ANDA is an act of patent infringement if the ANDA seeks approval to manufacture, use, or sell a drug that is claimed in a patent or the use of which is claimed in a patent. 35 U.S.C. § 271(e).

> process allows a generic drug company to challenge a drug patent by alleging the patent is invalid. . . . Accordingly, given that there is a statute in place that encourages generic drug companies to challenge patents, [the plaintiff's] copying argument is weak.

Id. at *138.

This Court acknowledges that "more than the mere fact of copying by an accused infringer is needed to make that action significant to a determination of the obviousness issue." Cable Electric Prods, Inc. V. Genmark, Inc., 770 F.2d 1015, 1028 (Fed. Cir. 1985). For instance, the Federal Circuit has explained that if copying "occurred out of a general lack of concern for patent property, . . . it weighs neither for or against the nonobviousness of a specific patent." Id. If it occurred out of a reasonable belief that the invention was unpatentable because it was obvious, it "only arguably demonstrat[es] obviousness." Id.; see also Roger Schecter and John Thomas, Principles of Patent Law 165 (2d ed.).

Importantly, the copier's motivation is a question of fact. The answer to this factual question may affect the weight that should be accorded to evidence of copying, but the mere fact that this case arises under the Hatch-Waxman act does not render the evidence entirely irrelevant. Pfizer will be permitted to introduce evidence of copying. Teva can introduce evidence as to its motivation for copying the invention. Once this Court has heard the evidence and arguments from both

parties, it will make a determination about the proper weight to accord to the evidence.

Accordingly, Teva's in limine motion No. 3 to preclude Pfizer from submitting evidence relating to copying will be denied.

/s/ John C. Lifland, U.S.D.J.

Dated: October 26, 2006